DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

EXHIBIT 10

Food and Drug Administration
Rockville MD 20857

IND 58,500

Inveresk Research (North America) Inc
Attention: David J. Dempsey
Director, Regulatory Affairs
4470 Redwood Hwy Ste 101
San Rafael, CA 94903

JUL 9

JUL 15 1999

INVERESK RESEARCH

Dear Mr. Dempsey:

We acknowledge receipt of your Investigational New Drug Application (IND) submitted pursuant to section 505(i) of the Federal Food, Drug, and Cosmetic Act. Please note the following identifying data:

IND Number Assigned: 58,500

Sponsor: Medivir AB

Name of Drug: ME-609 Cream (Acyclovir 5%/Hydorcortisone 1%)

Date of Submission: June 18, 1999

Date of Receipt: June 21, 1999

Studies in humans may not be initiated until 30 days after the date of receipt shown above. If, within the 30-day waiting period, we identify deficiencies in the IND that require correction before human studies begin or that require restriction of human studies until correction, we will notify you immediately that the study may not be initiated ("clinical hold") or that certain restrictions must be placed on it. In the event of such notification, you must continue to withhold, or to restrict, such studies until you have submitted material to correct the deficiencies, and we have notified you that the material you submitted is satisfactory.

It has not been our policy to object to a sponsor, upon receipt of this acknowledgement letter, either obtaining supplies of the investigational drug or shipping it to investigators listed in the IND. However, if the drug is shipped to investigators, they should be reminded that studies may not begin under the IND until 30 days after the IND receipt date or later if the IND is placed on clinical hold.

As sponsor of this IND, you are responsible for compliance with the Federal Food, Drug, and Cosmetic Act and the implementing regulations (Title 21 of the Code of Federal Regulations). Those responsibilities include (1) reporting any unexpected fatal or life-threatening adverse experience associated with use of the drug by telephone or fax no later than 7 calendar days after initial receipt of the information (21 CFR 312.32(c)(2)); (2) reporting any adverse experience with use of the drug that is both serious and unexpected in writing no later than 15 calendar days of initial receipt of the information (21 CFR 312.32(c)(1)); and (3) submitting annual progress reports (21 CFR 312.33).

Please forward all future communications concerning this IND in quadruplicate, identified by the above IND number, and addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Viral Drug Products, HFD-530
Attention: Document Control Room
5600 Fishers Lane
Rockville, Maryland 20857

Should you have any questions concerning this submission, please contact Melissa Truffa, R.Ph., at (301) 827-2335.

Sincerely,

Anthony W. DeCicco
Supervisory Consumer Safety Officer
Division of Anti-Viral Drug Products, HFD-530
Office of Drug Evaluation IV
Center for Drug Evaluation and Research